[redacted]IN A CIVIL ACTION COURT OF COMMON PLEAS, CUYAHOGA COUNTY JUSTICE CENTER
CLEVELAND, OHIO 44113

CASE NO. CV07643786 D1 CM

SUMMONS NO. 11199389

Rule 4 (B) Ohio Rules of Civil Procedure

DAVID MICHEL ET AL
VS
STRYKER CORP. ET AL

PLAINTIFF

DEFENDANT

# SUMMONS

STRYKER CORPORATION
2825 AIRFIELD BLVD
KALAMAZOO MI 49002-0000

You have been named defendant in a complaint (copy attached hereto) filed in Cuyahoga County Court of Common Pleas, Cuyahoga County Justice Center, Cleveland, Ohio 44113, by the plaintiff named herein.

You are hereby summoned and required to answer the complaint within 28 days after service of this summons upon you, exclusive of the day of service.

Said answer is required to be served on:

Plantiff's Attorney

WILLIAM CRAIG BASHEIN
35TH FLOOR TERMINAL TOWER

50 PUBLIC SQUARE
CLEVELAND, OH 44113-0000

Said answer is required to be served on Plaintiff's Attorney (Address denoted by arrow at left.)

Your answer must also be filed with the court within 3 days after service of said answer on plaintiff's attorney.

If you fail to do so, judgment by default will be rendered against you for the relief demanded in the complaint.

Case has been assigned to Judge:

TIMOTHY E MCMONAGLE
Do not contact judge. Judge's name is given for attorney's reference only.

GERALD E. FUERST
Clerk of the Court of Common Pleas

DATE
Dec 7, 2007

By _____ Deputy

COMMON PLEAS COURT CUYAHOGA COUNTY OHIO

COMPLAINT FILED 12/05/2007

MSN130

IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

DAVID MICHEL
5050 Cofton
Solon, Ohio 44139

and

LISA MICHEL
5050 Cofton
Solon, Ohio 44139

Plaintiffs

vs.

STRYKER CORPORATION
2825 Airfield Boulevard
Kalamazoo, Michigan 49002

and

HOWMEDICA OSTEONICS CORP.
c/o CT Corporation System
1300 East 9th Street
Cleveland, Ohio 44114

and

STRYKER ORTHOPAEDICS
c/o Howmedica Osteonics Corp.
325 Corporate Drive
Mahway, New Jersey 07430

Defendants

CAS Complaint
TIMOTHY E MCMONAG
CV 07 643786
JUI

COMPLAINT

[JURY DEMAND ENDORSED HEREON]



Now come the Plaintiffs, by and through counsel, and for their Complaint against the Defendants state as follows:

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## PARTIES

1. Plaintiff, David Michel, is and was, at all relevant times herein, a resident and citizen of the City of Solon, Ohio. On or about April 27, 2004, Plaintiff was implanted with a Trident Ceramic Acetabular System total artificial hip that was manufactured and/or placed into the stream of commerce by the Defendants. Plaintiff Elisa Michel is and was at all times herein relevant the wife of Plaintiff David Michel.

2. Defendant Stryker Corporation is a publicly traded corporation that has its principal place of business in Kalamazoo, Michigan. Defendant regularly transacts business and/or maintains a presence in Cuyahoga County and elsewhere in the State of Ohio.

3. Defendant Howmedica Osteonics Corporation is a wholly owned subsidiary of Defendant Stryker Corporation that has its principal place of business in New Jersey. Defendant regularly transacts business and/or maintains a presence in Cuyahoga County and elsewhere in the State of Ohio.

4. Defendant Stryker Orthopaedics is the registered trade name of Defendant Howmedica Osteonics Corporation. Defendant regularly transacts business and/or maintains a presence in Cuyahoga County and elsewhere in the State of Ohio.

## FACTUAL BACKGROUND

5. The Defendants designed, tested, manufactured, distributed and placed into the stream of commerce the Trident Ceramic Acetabular System. The Trident Ceramic Acetabular System is a ceramic on ceramic total hip replacement prosthesis.

6. The Trident Ceramic Acetabular hip prosthesis was marketed as having an extended life and as the implant of choice for active individuals who needed a total hip replacement.

7. Plaintiff David Michel, a man of approximately forty-five (45) years of age,

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underwent a total hip replacement utilizing the Trident Ceramic Acetabular hip prosthesis on or about April 27, 2004.

8. A loud squeaking noise subsequently developed when Plaintiff ambulated due to what is now known as defects in the Stryker ceramic implant hip. Plaintiff was advised that Defendants were responsible for the problems of squeaking associated with the Stryker ceramic on ceramic hip implant systems when he received a copy of a letter dated October 9, 2006 from Stryker Orthopaedics directed to his treating physician, Dr. Kim Stearns. A copy of the letter is attached hereto as *Exhibit A*.

**FIRST CAUSE OF ACTION**
**Strict Liability**

9. Plaintiffs restate the allegations set forth in Paragraphs 1 through 8 of their Complaint as if fully rewritten herein.

10. The Trident Ceramic Acetabular hip prosthesis manufactured and/or supplied by Defendants was defective in manufacture or construction in that, when it left the hands of said Defendants, it deviated in a material way from its manufacturing performance standards and/or it differed from otherwise identical units manufactured to the same design formula.

11. The Trident Ceramic Acetabular hip prosthesis manufactured and/or supplied by said Defendants was defective in design and/or formulation in that, when it left the hands of said Defendants, the foreseeable risks exceeded the benefits associated with the design and/or formulation.

12. Alternatively, the Trident Ceramic Acetabular hip prosthesis supplied by said Defendants was defective in design and/or formulation in that it was more dangerous than an ordinary consumer would expect when used in its intended or reasonably foreseeable manner.

13. The Trident Ceramic Acetabular hip prosthesis manufactured and/or supplied by

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said Defendants was defective due to inadequate warning or instruction in that, when it left the hands of said Defendants, Defendants knew or should have known that the product was such as to create a risk of harm to consumers and Defendants failed to exercise reasonable care to warn of said risk.

14. The Trident Ceramic Acetabular hip prosthesis manufactured and/or supplied by said Defendants was defective due to inadequate post-marketing warnings and/or instructions in that, when it left the hands of Defendants they knew or should have known the risk involved with the use of said product and failed to exercise reasonable care to provide adequate warning to users of the product.

15. The Trident Ceramic Acetabular hip prosthesis manufactured and/or supplied by said Defendants was defective in that it did not conform to the express and/or implied representations of Defendants, when it left their hands, that it was safe for use by consumers and free of squeaks, noises, and other annoying defects.

16. As a direct and proximate result of the defective condition of the Trident Ceramic Acetabular hip prosthesis, as manufactured by the said Defendants, Plaintiffs suffered serious injury and disability, including substantial medical expenses, pain and discomfort, an inability to perform usual functions, and a loss of enjoyment of life, which are reasonably certain to be permanent and ongoing.

## SECOND CAUSE OF ACTION
### Negligence

17. Plaintiffs restate the allegations set forth in Paragraphs 1 through 16 of their Complaint as if fully rewritten herein.

18. Defendants had a duty to exercise reasonable care in the manufacture, design and/or supply of the Trident Ceramic Acetabular hip prosthesis into the stream of worldwide

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commerce, including a duty to exercise care to assure that the product was safe for its intended use by consumers and free of defects. Said Defendants negligently failed to exercise ordinary care in the manufacture, testing, design and/or supply of the Trident Ceramic Acetabular hip prosthesis.

19. Said Defendants negligently failed in their duty to exercise reasonable care in the provision of an adequate warning as to the risks of the Trident Ceramic Acetabular hip prosthesis that they knew or should have known.

20. Said Defendants maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the Trident Ceramic Acetabular hip prosthesis when they knew or should have known of said risks.

21. As a direct and proximate result of said Defendants' negligent conduct, Plaintiffs suffered injury, disability, expense and other damages as aforementioned.

**THIRD CAUSE OF ACTION**
**Breach of Implied Warranty**

22. Plaintiffs restate the allegations set forth in Paragraphs 1 through 21 of their Complaint as if fully rewritten herein.

23. Defendants are in the business of manufacturing and/or supplying and/or placing into the stream of commerce Trident Ceramic Acetabular hip prosthesis for consumers in Ohio and elsewhere.

24. By placing Trident Ceramic Acetabular hip prosthesis into the stream of commerce, said Defendants impliedly warranted that the Trident Ceramic Acetabular hip prosthesis was fit and safe for its intended use and free of defects.

25. The Trident Ceramic Acetabular hip prosthesis placed into the stream of commerce by said Defendants was defective in that it was not fit and safe for its intended use.

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26. The defect in the Trident Ceramic Acetabular hip prosthesis manufactured and/or supplied by said Defendants was present at the time the product left the hands of said Defendants.

27. Said Defendants breached the implied warranty for the Trident Ceramic Acetabular hip prosthesis because said products was defective, unmerchantable and not fit for its intended purpose.

28. Plaintiff was a foreseeable user of the Trident Ceramic Acetabular hip prosthesis.

29. As a direct and proximate result of said Defendants' breach of implied warranty, Plaintiffs suffered injury, disability, expense, economic loss and other damages as aforementioned.

**FOURTH CAUSE OF ACTION**
**Breach of Express Warranty**

30. Plaintiffs restate the allegations set forth in Paragraphs 1 through 29 of their Complaint as if fully rewritten herein.

31. Defendants expressly warranted to Plaintiff that the Trident Ceramic Acetabular hip prosthesis, which it designed, developed, manufactured and sold to Plaintiff was of merchantable quality, fit and safe, and otherwise not injurious to the Plaintiff's health and well being.

32. The Trident Ceramic Acetabular hip prosthesis implanted in Plaintiff was unsafe, unmerchantable, unfit for use in the body and otherwise injurious to Plaintiff.

33. Through their sale of Trident Ceramic Acetabular System, Defendants were merchants.

34. Defendants breached express warranties of merchantability in the sale of Trident Ceramic Acetabular hip prosthesis to Plaintiff in that said product was not fit for its ordinary

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purposes described above.

35. As a direct and proximate result of Defendants' breach of their express warranties as described herein, Plaintiff suffered substantial and severe harm, injury, and damage as aforementioned.

**FIFTH CAUSE OF ACTION**
**Fear of Future Product Failure**

36. Plaintiffs restate the allegations set forth in Paragraphs 1 through 35 of their Complaint as if fully rewritten herein.

37. Defendants placed into the stream of commerce defective Trident Ceramic Acetabular hip prosthesis knowing that said product was not fit for its intended purposes and knowing that said product caused attendant medical problems as described herein.

38. Defendants knew that Plaintiff would suffer mental distress and anxiety upon learning that said Trident Ceramic Acetabular hip prosthesis possessed a likelihood of failure and the development of attendant medical problems as described herein, thereby causing serious bodily injury or possible death.

39. Defendants' conduct in manufacturing, distributing, wholesaling, fabricating, advertising, promoting, modifying, and placing on the market and into the stream of commerce known defective products has directly and proximately caused Plaintiff to suffer severe and debilitating mental distress and anxiety.

**SIXTH CAUSE OF ACTION**
**Misrepresentation**

40. Plaintiffs restate the allegations set forth in Paragraphs 1 through 39 of their Complaint as if fully rewritten herein.

41. Defendants purposefully, negligently, and/or carelessly made the foregoing

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misrepresentations without a reasonable basis or legitimate support for them.

42. Defendants were aware that they did not possess information on which to accurately base the foregoing representations and concealed from Plaintiff the true facts as well as that there was no reasonable basis for making said representation herein.

43. When Defendants made the foregoing representations, they knew or should have known they were unsubstantiated, unverifiable, and/or outright false. Defendants nevertheless proceeded to make the misrepresentations even though they knew that the consumers, including Plaintiffs, were substantially certain to rely upon them and suffer grave harm as a result.

44. In reliance upon the purposeful misrepresentations and concealments by the Defendants, Plaintiff was induced to and did subject himself to the use of the aforementioned product. If Plaintiff had known of the true facts, he would not have taken such action and risk. Plaintiff reasonably relied on misrepresentations and omissions that were made by individuals and entities on behalf of Defendants who are in a position to know the true facts.

45. As a result of the foregoing deliberate and/or negligent misrepresentations and concealments by Defendants, Plaintiff suffered injuries and damages as previously alleged herein.

## SEVENTH CAUSE OF ACTION
## Loss Of Consortium

46. Plaintiff Elisa Michel restates the allegations set forth in Paragraphs 1 through 45 of the Complaint as if fully rewritten herein.

47. Plaintiff Elisa Michael is and was at all times herein relevant the wife of Plaintiff David Michel.

48. As a direct and proximate result of the above mentioned conduct, Elisa Michel was deprived of the society, support, companionship and consortium of her husband and she will

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continue to suffer such losses into the indefinite future.

**PRAYER**

**WHEREFORE**, Plaintiffs pray for judgment against Defendants, jointly and severally, as follows:

a. For compensatory damages in excess of $25,000.00 to be proven at time of trial;
b. For punitive damages in excess of $25,000.00 to be proven at the time of trial;
c. For pre-judgment and post-judgment interest on the above general and special damages;
d. For costs of this suit, attorneys' fees, and litigation expenses; and
e. All other relief that Plaintiff may be entitled to at equity or at law, including but not limited to a declaratory judgment and/or the funding of a medical monitoring program.

Pursuant to Rule 38(B), Ohio Rules of Civil Procedure, Plaintiffs hereby demand trial by jury on all issues.

Respectfully submitted,

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stryker
Orthopaedics

October 9, 2006

Kim L. Stearns, MD
Horizon Orthopaedic
2709 Franklin Boulevard, Ste 6E
Cleveland, OH 44113

Dear Dr. Stearns:

The clinical community has been discussing recent reports of an audible noise, such as a squeak, during motion, in a small number of patients who have received hard-on-hard bearings. We would like to communicate to you a recent update to both Stryker's package insert and patient labeling for the Trident ceramic-on-ceramic hip system. Included below are statements that have been added under the following sections: Potential Risks in the patient labeling; Patient Counseling Information and Safety Data in the package insert for ceramic liners. Stryker feels this information is important to share with you and your patients, as it is part of weighing the potential risks and benefits of surgery.

**Potential Risks (Patient Labeling)** - *An audible noise during motion, such as a squeak, has been reported for patients receiving a ceramic-on-ceramic bearing couple. A 0.6% rate of squeaking noise has been reported in the clinical study with the Trident® Alumina Insert.*

**Patient Counseling Information (Package Insert)** *Surgeons should inform patients about potential adverse events listed below. An audible noise during motion such as a squeak has been reported for patients receiving a ceramic-on-ceramic bearing couple. A 0.6% rate of squeaking noise has been reported in the prospective, controlled, multi-center clinical trial with the Trident® Alumina Insert.*

The incidence of squeaking is not unique to the Stryker implant systems and has also been associated with other hard on hard hip bearings. Our research indicates that Stryker's ceramic on ceramic hip implant systems have a survivorship of greater than 95% out to 8 years follow-up. The research also demonstrates high patient satisfaction, reduced rate of osteolysis and low rates of dislocation and deep joint infection.[1,2]

To date, our IDE clinical study shows no data that squeaking alone indicates a compromise in the mechanical integrity of the implant. While we are working to identify specific clinical circumstances that would lead to squeaking, our laboratory research suggests that the cause of squeaking is multi-factorial, including patient, surgical and implant variables. We will continue to evaluate reports of squeaking through our post market product surveillance procedures.

EXHIBIT
A

As always, we will continue to strive to achieve superior clinical results and be responsive to patient and customer needs. As your partner, we feel it is important for you to understand these clinical experiences, so that you can have the most informed discussions with your patients.

If you have any questions please contact William J. Cymbaluk, VP of Clinical Research, Quality Assurance and Regulatory Affairs, at (201) 831-6002.

Sincerely,

William J. Cymbaluk
VP of Clinical Research, Quality Assurance and Regulatory Affairs

[1] D'Antonio, J., Capello, W., Manley, M., Naughton, M., Sutton, K., "Alumina Ceramic Bearings for Total Hip Arthroplasty – Five Year Results of a Prospective Randomized Study," Clinical Orthopaedics and Related Research, Number 436, July 2005, pp. 164-171

[2] D'Antonio, J., Capello, W., Manley, M., Naughton, M., Sutton, K., "A Titanium-encased Alumina Ceramic Bearing for Total Hip Arthroplasty – 3 to 5 Year Results," Clinical Orthopaedics and Related Research, Number 441, December 2005, pp. 151-156